

STATUS OF CLAIMS

Claims 1-15 are pending.

Claims 1-15 stand rejected.

Claims 1, 8, 9, 10, 12 and 15 have been amended without prejudice.

REMARKS

Change of Correspondence Address

Applicant submits herewith a Request to change correspondence address. Applicant respectfully requests all correspondence regarding this application be addressed to the address associated with Customer Number 45,722.

Claim Amendments

Applicant has amended Claim 1 to recite, *inter alia*, "situating at least one absorbent apparatus containing at least one substance comprising saline substantially adjacent to said burned tissue." Support for such a limitation may be found throughout the specification as originally filed, such as at par. [35] (*"In an exemplary embodiment of the present invention, an ultrasonic transducer device may be used for enhancing the transdermal delivery of medicaments for the treatment of conditions, such as ... burned skin."*). Further support may be seen, for example, at pars. [37] and [38], where it teaches:

[38] The transdermal apparatus may be a pad, patch, bandage or wrap, and may contain any sort of substance, medication or combination of substances or medications suitable for use in the desired treatment.

[39] Medicants for such treatment may include, by way of non-limiting example only, saline.

Yet further support for this limitation may be seen in Fig. 11 and par. [75] (*"Referring to FIG. 11, an Ultrasonic patch or bandage containing saline 1110 (Transducer & Patch (TDD)) is mounted to the burn area on the skin of the abdomen 1120 and held in place by a strap 1130 over the test area."*).

Claim 1 has also been amended to recite, *inter alia*, "affixing at least one ultrasonic signal emitting device substantially adjacent to said at least one absorbent apparatus." Support for this amendment may also be found throughout the application as filed, such as at Fig. 1 and at par. [49] ("*As may be seen in FIG. 1, a wearable, non-invasive, ultrasonic-transdermal skin medicant delivery system is shown. Included in this system may be an ultrasonic applicator 1 placed directly over a transdermal apparatus or patch 2. Contact between the transducer device and the transdermal patch preferably promotes efficient acoustic energy transmission.*").

Claim 15 has been amended analogously. Claims 1, 8, 9, 10, 12 and 15 have also been amended to improve readability, and make more clear that burned tissue is being treated in the recited methods. Accordingly, no new matter has been presented.

Claim Rejections

Claims 1-7 stand rejected under 35 U.S.C. 102(e) as being anticipated by Babaev (United States Patent Application No. 2002/0156400). Claims 1 and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana (United States Patent No. 5,315,998). Claims 8-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Babaev in view of Bommannan (United States Patent No. 5,115,805). Claims 12 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Babaev in view of Mauchamp (United States Patent No. 6,537,224). Claim 13 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Babaev in view of Zhang (United States Patent Publication No. 2002/0096973). Applicant requests reconsideration and removal of these rejections for at least the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See, *M.P.E.P. §2131 citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Similarly, to establish a prima facie case of obviousness under 35 U.S.C. 103(a), all of the recited claim limitations must be taught or suggested in the prior art. See, 2143.03 citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) ("*All words in a claim must be considered in judging the patentability*

of that claim against the prior art.') and *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). The cited art fails to teach or suggest each of the limitations of any of the rejected claims – and hence fails to anticipate or render any of these claims unpatentably obvious as a matter of law.

Turning first to Claim 1, it recites, *inter alia*, “situating at least one absorbent apparatus containing at least one substance comprising saline substantially adjacent to said burned tissue.” Babaev fails to teach or suggest such a configuration.

Instead, Babaev sprays liquid onto a wound. More particularly, Babaev teaches a spray of liquid particles produced by contact of the liquid with a free end surface of an ultrasonic transducer is directed onto a wound. See, *par. [0016]*. Accordingly, Babaev fails to teach or suggest “situating at least one absorbent apparatus containing at least one substance comprising saline substantially adjacent to said burned tissue.” The Office action acknowledges this deficiency of Babaev, where it admits, “Babaev discloses the claimed invention except for the containment of a substance within an absorbent pad.” *April 18, 2007 Office action*, pg. 5, ll. 11-14. In an effort to remedy this admitted shortcoming of Babaev, the Office action attempts to import select portions of Bommannan. This reliance is without merit though.

A patent claim is not proved obvious merely by showing that each of its several elements was, independently, in the prior art. See, *KSR Int'l Co. V. Teleflex Inc.*, 127 S. Ct. 1727 citing *United States v. Adams*, 86 S. Ct. 708. Rather, an explicit analysis of as to whether there was an apparent reason to combine the known elements in the fashion claimed needs to be made. See, *KSR Int'l Co. V. Teleflex Inc.*, 127 S. Ct. 1727 citing *In re. Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

First, Applicant notes Bommannan nowhere mentions that burns may be treated with its methodology. Instead, it is concerned with enhancing the rate of permeation through the skin of “pharmacologically active agents” or “drugs”. See, *e.g.*, col. 4, ll. 6-9; see also, col. 5, ll. 17-25. As used in Bommannan, these terms refer to chemical

materials or compounds suitable for transdermal or transmucosal administration which can either (1) have a prophylactic effect on the organism and prevent an undesired biological effect such as preventing an infection, (2) alleviates a condition caused by a disease such as alleviating pain caused as a result of a disease, or (3) either alleviates or completely eliminates the disease from the organism. See, col. 5, l. 61 – col. 6, l. 27. Nowhere does Bommannan teach or suggest that its methodology be used to treat burned tissue. Accordingly, Applicant submits a skilled artisan would not have turned to Bommannan for treating burned tissue, as a motivation for increasing the permeability of un-burned biological membranes is of little moment in treating tissue burns.

Further, even if Bommannan's teachings may be generalized to include treating burned tissue, a proper reason for modifying Babaev to incorporate the recited "situating at least one absorbent apparatus containing at least one substance comprising saline substantially adjacent to said burned tissue" is lacking.

Each prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). A *prima facie* case of obviousness can be rebutted where the cited art teaches away from the claimed invention in any material respect. See, *In re Haruna*, 249 F.3d 1327, 58USPQ2d 1517 (Fed. Cir. 2001). A reference teaches away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the applicant. *In re Haruna*, 249 F.3d 1327, 58USPQ2d 1517.

Babaev expressly teaches away from the recited method of Claim 1 – in at least that it leads a skilled artisan in a direction divergent from that path taken by the Applicant (and as is presently recited in the methodology of Claim 1). More particularly, Babaev explains that two different therapeutic uses of ultrasound are aerosol mist production and contact physiotherapy. See, *par.* [0003]. Babaev goes on to explain that in contact physiotherapy, ultrasonic waves are applied through a coupling medium and into the tissue. See, *par.* [0005]. Babaev, then goes on to expressly teach that,

contrary to the recited method of Claim 1, contact physiotherapy is not suitable for use with burns and other wounds. See, par. [0006]. More particularly, Babaev teaches:

current techniques of medical physiotherapy using ultrasonic waves are limited by the necessity of providing a direct contact interface between the ultrasonic transducer and the tissue to maintain an effective transmission of the ultrasonic waves from the transducer to the tissue. The necessity of direct contact with or without a coupling medium makes current methods undesirable. Some tissue conditions may be accessible to contact ultrasound devices but would be **impractical for contact ultrasound treatment**. For example, **fresh or open wounds resulting from trauma, burns**, surgical interventions **are not suitable for direct contact ultrasound treatment** because of the structural of the structural nature of the open wound and the **painful condition** associated with those wounds. Moreover, conventional contact ultrasound may have **a destructive effect on these types of open wounds** due to the close proximity of an oscillating tip of an ultrasonic transducer relative to the already damaged tissue surface. (Emphasis added).

Accordingly, Babaev expressly teaches against the use of contact ultrasound for treating open wounds and burns, instead proposing an approach that projects a spray akin to an aerosol mist.

Again, and in contrast to these Babaev teachings, Claim 1 recites, *inter alia*:

situating at least one absorbent apparatus containing at least one substance comprising saline substantially adjacent to said burned tissue; ... [and]

applying at least one ultrasonic signal emitted from said at least one ultrasonic signal emitting device to said at least one absorbent apparatus to effect movement of at least a portion of said at least one substance into said burned tissue.

Accordingly, Babaev leads a skilled artisan in a direction divergent from the path that was taken by the Applicant, and is recited by Claim 1 – at least by virtue that Claim 1 calls for situating at least one absorbent apparatus containing a substance substantially adjacent burned tissue, and applying ultrasound thereto, and Babaev

teaches that direct contact ultrasound physiotherapy is impractical for burn treatment, and may even be destructive.

For purposes of completeness, Applicant notes Tachibana, like Bommannan, is silent with regard to wound or burn treatment, and instead is concerned with enhancing the therapy of various diseases. *See, col. 1, ll. 6-11.*

Accordingly, Applicant submits Babaev both alone, and in combination with Bommannan, fail to anticipate or render Claim 1 unpatentably obvious, at least by reason that: (1) Babaev fails to teach or suggest each of the limitations of Claim 1; and (2) Babaev teaches against the recited method of Claim 1, at least by reason that Babaev expressly teaches against using contact ultrasonic physiotherapy to treat burns and other open wounds. Wherefore, Applicant requests reconsideration and removal of the rejections of Claim 1. Applicant also requests reconsideration and removal of the rejections of Claims 2-14 as well, at least by virtue of these claims' ultimate dependency upon a patentably distinct base Claim 1.

Turning now to Claim 15, it analogously recites:

A method for treating burned tissue, comprising:
 situating an absorbent material containing apparatus
 containing at least one medicament in at least partial contact
 with said burned tissue;
 situating at least one ultrasonic signal emitting device
 in at least partial contact with said absorbent material
 containing apparatus; and,
 applying at least one ultrasonic signal emitted from
 said at least one ultrasonic signal emitting device to said
 absorbent material containing apparatus, so as to effect
 movement of at least a portion of said at least one
 medicament into said burned tissue.

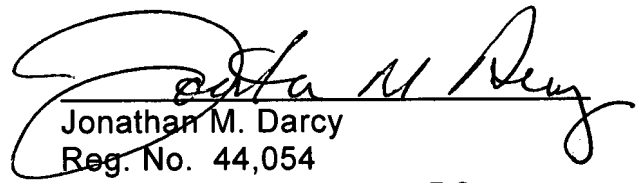
Accordingly, Applicant requests reconsideration and removal of the rejections thereof for at least the forgoing reasons as well.

CONCLUSION

Wherefore, Applicant believes he has addressed all outstanding grounds raised by the Examiner and respectfully submits the present case is in condition for allowance, early notification of which is earnestly solicited.

Should there be any questions or outstanding matters, the Examiner is cordially invited and requested to contact Applicant's undersigned attorney at his number listed below.

Respectfully submitted,


Jonathan M. Darcy
Reg. No. 44,054
Plevy, Howard & Darcy, PC
P.O. Box 226
Fort Washington, PA 19034

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